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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Michael L Goldman
Nixon Peabody LLP
Clinton Square
PO Box 31051
Rochester, NY 14603

EXAMINER
KUBELIK, ANNE R

ART UNIT	PAPER NUMBER
1638	9

DATE MAILED: 03/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/597,840	Applicant(s) QIU ET AL.	
	Examiner Anne Kubelik	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *38-51* is/are pending in the application.

4a) Of the above claim(s) *40,42-45 and 51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38,39,41 and 46-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Applicant's election with traverse of Group II (claims 38-39, 41 and 46-50) in Paper No. 8 is acknowledged. The traversal is on the ground(s) that the restriction requirement does not following MPEP provisions regarding linking claims. Applicant also argues that the claims do not specify a single species of nucleic acid molecule and that thus it is irrelevant that individual sequences are distinct inventions. Applicant argues that the inventions are not unrelated because claim 39 indicates that the hypersensitive elicitor protein can be from "mixtures" of the four bacteria listed and because different methods have identical functions. Lastly Applicant questions the classification of the Groups.

This is not found persuasive. Claims 38-39 and 46-50 were effectively treated as linking claims in that they were associated with multiple Groups. With respect to the argument that the claims do not specify a single species of nucleic acid molecule, the claims are drawn to transformation with nucleic acids. The nucleic acid are from different bacterial species; thus, the nucleic acids must be of different sequence. With respect to the argument that the inventions are not unrelated, claim 38 is drawn to transformation with a nucleic acid encoding **a** hypersensitive elicitor **protein**; a single protein cannot be derived from a mixture of bacteria. The different methods have different modes of operation because they necessarily use different starting material, *i.e.*, nucleic acids from different bacteria. Different classification is only one of the reasons for restriction; the instant groups also require different searches (on nucleic acids from different bacteria) and are recognized divergent subject matter (because the different methods require different starting material).

Claims 40, 42-45 and 51 are withdrawn from consideration as being drawn to nonelected inventions. Claims 38-39, 41 and 46-50 are examined to the extent they read on transformation with a nucleic acid encoding a hypersensitive response elicitor from *Erwinia amylovora*.

The requirement is still deemed proper and is therefore made FINAL.

2. The drawings are objected to for the reasons indicated on accompanying form PTO 948. Applicant is required to submit acceptable corrected drawings within the time period set in this Office action. See 37 CFR 1.85(a). Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 38-39, 41 and 46-50 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to a multitude of DNA molecules that encode hypersensitive response proteins from *E. amylovora*. In contrast, the specification only describes a coding sequence from *E. amylovora* that comprises SEQ ID NO:4. Applicant does not describe other DNA molecules encompassed by the claims, and the structural features that distinguish all such nucleic acids from other nucleic acids are not provided.

The instant specification fails to describe all *E. amylovora* nucleic acids that encode hypersensitive response elicitor proteins. For example, the instant specification fails to teach the HrpW gene (Kim et al, 1998, J. Bacteriol. 180:5203-5210) or the *dspE* or *dspF* genes (Bogdanove et al, 2001, US Patent 6,228,644), all of which encode hypersensitive response elicitor proteins.

Hence, Applicant has not, in fact, described DNA molecules that encode hypersensitive response proteins from *E. amylovora* within the full scope of the claims, and the specification fails to provide an adequate written description of the claimed invention.

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, it is not clear that Applicant was in possession of the genus claimed at the time this application was filed.

See *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed, Cir. 1997):

> The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA .... Accordingly, the specification does not provide a written description of the invention ....

and at pg 1406:

> a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicted, does not suffice to define the genus because it is only an indication of what the genes does, not what it is.

See *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at page 1021:

> A gene is a chemical compound, albeit a complex one, and ... conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials .... Conception does not occur unless one has a mental picture of the structure of the chemical or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. It is not sufficient to define it solely by it principal biological property, *e.g.*, encoding human erythropoietin, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property.

5. Claims 38-39, 41 and 46-50 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn to a method of enhancing growth in plants by growing a plant or seed that has been transformed with a nucleic acid that encodes a hypersensitive response elicitor protein from *E. amylovora*.

The instant specification, however, only provides guidance for a nucleic acid that encodes a hypersensitive response elicitors from *E. amylovora* (SEQ ID NO:4) and the sequence of the protein encoded by that nucleic acids (SEQ ID NO:3). The instant specification cites references detailing the isolation of hypersensitive response elicitor proteins from various bacteria (pg 22-23). The instant specification provides guidance for topical application of the *E. amylovora* hypersensitive response elicitor to tomato seeds and analysis of the effect of that application on plant height (examples 1 and 2), topical application of the *E. amylovora* hypersensitive response elicitor to tomato plants and analysis of the effect of that application on plant height (examples 3 and 4), topical application of the *E. amylovora* hypersensitive response elicitor to tomato seeds and analysis of the effect of that application on seed germination (example 5), topical application to tomato seeds or plants of the *E. amylovora* hypersensitive response elicitor prepared from

transformed *Escherichia coli* and analysis of the effect of that application on plant height (examples 6, 7 and 9), topical application of the *E. amylovora* hypersensitive response elicitor to potato tubers and analysis of the effect of that application on plant height (example 8), topical application of the *E. amylovora* hypersensitive response elicitor to raspberry and analysis of the effect of that application on fruit coloration and ripening (examples 10), topical application of the *E. amylovora* hypersensitive response elicitor to snap bean, cucumber, cotton, eggplant, rice, soybean, strawberry, jalapeno pepper, tobacco or winter wheat plants or seeds and analysis of the effect of that application on growth enhancement or yield increase (examples 11-17 and 20-23), and topical application of the *E. amylovora* hypersensitive response elicitor to tomato or strawberry plants and analysis of the effect of that application on maturity(examples 18-19).

The instant specification fails to provide guidance for plant or seed that has been transformed with a nucleic acid that encodes a hypersensitive response elicitor protein from *E. amylovora* or for methods of plant transformation. The instant specification fails to provide guidance for methods of enhancing growth in a plant by transformation with a hypersensitive response elicitor gene from *E. amylovora*. The instant specification also fails to provide guidance for *E. amylovora* hypersensitive response elicitor genes other than SEQ ID NO:4.

Constitutive elicitor production can be lethal to a plant; thus, transformation of a plant with a gene encoding an elicitor protein also requires an inducible promoter (Keller et al, 1999, Plant Cell 11:223-235, see pg 224, left column paragraph 1). The instant specification fails to teach such promoters or how lethality can be prevented without them.

Overexpression of a gene in plants is unpredictable. Sweetlove et al (1996, Biochem. J. 320:493-498) found no differences in starch content, tuber number, tuber weight, or metabolite

content between potatoes transformed with a gene encoding ADP-glucose pyrophosphorylase and potatoes from control plants, even though the activity of the enzyme was four-fold higher in the transformed plants (pg 495, entire pg, and pg 497, right column, paragraph 3). Thiele et al (1999, Plant Physiol. 120:73-81) teach that in potato plants transformed with the *Arabidopsis* phytochrome B gene, the endogenous phytochrome B transcript levels were not significantly affected (pg 75, right column, paragraph 3, and Fig. 1).

Given the claim breath, unpredictability, and lack of guidance as discussed above, undue experimentation would be required to screen through a multitude of transgenic plants to identify those with enhanced growth, if such can even be produced by the claimed methods.

See *Genentech, Inc. v. Novo Nordisk, A/S*, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that disclosure of a "mere germ of an idea does not constitute [an] enabling disclosure", and that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

Thus, the claims are not enabled for a method of enhancing growth in plants by growing a plant or seed that has been transformed with a nucleic acid that encodes a hypersensitive response elicitor protein from *E. amylovora*.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 38-39, 41 and 46-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections.

Claim 38 is indefinite in its recitation of "conditions effective to enhance plant growth". The conditions effective to enhance growth of transformed plants are not defined in the specification. It is also not clear to what the growth is being compared.

It is not clear how a DNA molecule that encodes a polypeptide (as claimed in claim 37) can also encode mixtures of polypeptides (as claimed in dependent claim 39).

Claim 41 is indefinite in its recitation of "corresponds". It is not clear if this means the protein is from *E. amylovora* or where it is from.

It is not clear in the method of claim 38 what one does with the transgenic plant of line 3, as only the transgenic seed of line 3 is used in the second step of the method.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 38-39, 41 and 49-50 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 15-16 of U.S. Patent No. 6,174,717. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would be obvious to grow the plant of the issued patent or seed

thereof, which plant is transformed with a nucleic acid that encodes a hypersensitive response elicitor protein from *E. amylovora*, thereby practicing the method of the instant application, which method entails enhancing growth in plants by growing a plant or seed that has been transformed with a nucleic acid that encodes a hypersensitive response elicitor protein from *E. amylovora*.

10. Claims 38-39, 41 and 46-50 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11-16 of U.S. Patent No. 6,228,644. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would be obvious and necessary to grow the plants and seeds of the issued patent, which plants and seeds are transformed with a nucleic acid that encodes a hypersensitive response elicitor protein from *E. amylovora*, thereby practicing the method of the instant application, which method entails enhancing growth in plants by growing a plant or seed that has been transformed with a nucleic acid that encodes a hypersensitive response elicitor protein from *E. amylovora*. The plants of both the issues patent and the instant application include the same plant species.

11. Claims 38-39, 41 and 45-50 are free of the prior art, given the failure of the prior art to teach or suggest a method of enhancing growth in plants by transforming a plant or seed with a nucleic acid that encodes a hypersensitive response protein from *E. amylovora*.

Conclusion

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, Kimberly Davis, at (703) 305-3015.

Anne R. Kubelik, Ph.D.
March 22, 2002

Amy Nelson

AMY J. NELSON, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600